



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0736]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tracking Network for PETNet, LivestockNet, and SampleNet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0680. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Cappezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tracking Network for PETNet, LivestockNet, and SampleNet

OMB Control Number 0910-0680--Revision

The Center for Veterinary Medicine and the Partnership for Food Protection developed a Web-based tracking network (the tracking network) to allow Federal, State, and Territorial regulatory and public health Agencies to share safety information about animal food. Information is submitted to the tracking network by regulatory and public health Agency employees with membership rights. The efficient exchange of safety information is necessary because it improves early identification and evaluation of a risk associated with an animal food product. We use the information to assist regulatory Agencies to quickly identify and evaluate a risk and take whatever action is necessary to mitigate or eliminate exposure to the risk. Earlier identification and communication with respect to emerging safety information may also mitigate the potential adverse economic impact for the impacted parties associated with such safety issues. The tracking network was developed under the requirements set forth under section 1002(b) of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-085). Section 1002(b) of FDAAA required FDA, in relevant part, to establish a pet food early warning alert system.

Currently we receive two types of reports via the tracking network: (1) Reports of pet food-related illness and product defects associated with dog food, cat food, and food for other pets, which are submitted via the Pet Event Tracking Network (PETNet); and (2) reports of animal food-related illness and product defects associated with animal food for livestock animals, aquaculture species, and horses, which are submitted via LivestockNet. We are revising

the collection to include a third type of report that would be submitted via "SampleNet."

SampleNet will collect reports about animal food laboratory samples considered adulterated by State or FDA regulators. SampleNet will allow Federal, State, and Territorial regulatory and public health Agencies to share laboratory data related to adulterated samples for purposes of surveillance, mitigation, work planning, and supporting the animal food standard requirements.

PETNet and LivestockNet reports share the following common data elements, the majority of which are drop down menu choices: Product details (product name, lot code, product form, and the manufacturer or distributor/packer (if known)), the species affected, number of animals exposed to the product, number of animals affected, body systems affected, product problem/defect, date of onset or the date product problem was detected, the State where the incident occurred, the origin of the information, whether there are supporting laboratory results, and contact information for the reporting member (i.e., name, telephone number will be captured automatically when member logs in to the system). For the LivestockNet report, additional data elements specific to livestock animals will be captured: Product details (indication of whether the product is a medicated feed under 21 CFR 558.3(b)(8), product packaging, and intended purpose of the product), class of the animal species affected, and production loss. For PETNet reports, the only additional data field is the animal life stage. The proposed SampleNet reports will have the following data elements, many of which are drop down menu choices: Product information (product name, lot code, guarantor information, date and location of sample collection, and product description); laboratory information (sample identification number, the reason for testing, whether the food was reported to the Reportable Food Registry, who performed the analysis); and results information (analyte, test method, analytical results, whether

the results contradict a label claim or guarantee, and whether action was taken as a result of the sample analysis).

Description of Respondents: Respondents to the collection of information are Federal, State, and Territorial regulatory and public health Agency employees with membership access to the Animal Feed Network.

In the Federal Register of March 15, 2016 (81 FR 13794), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
PETNet	20	5	100	0.25 (15 minutes)	25
LivestockNet	20	5	100	0.25 (15 minutes)	25
SampleNet	20	5	100	0.25 (15 minutes)	25
Total					75

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on our experience with the tracking network over the past 3 years. We estimate that we will receive an average of 5 submissions from 20 respondents for each type of report, and that it will take 15 minutes (0.25 hour) per response.

Dated: April 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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